CERTIFICATE OF TRANSMITTAL

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Kathy Hinckley

PATENT

Applicant: Donald E. Bobo, Jr.
Serial No.: 10/021,132
Filed: October 29, 2001
Title: **METHODS AND APPARATUS FOR PROVIDING MEDICAMENT TO TISSUE**
Examiner: Shay, David M.
Group Art Unit: 3735
Confirmation No.: 2468
Atty. Docket No.: CVG-5637

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

REPLY BRIEF UNDER 37 CFR § 41.41

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer mailed May 12, 2008, please consider the Reply Brief contained herein. It is believed that this Reply Brief addresses all outstanding issues; that entry of this Reply Brief is proper; and that the preparation and mailing of a Decision On Appeal is now in order.

The fee of $500 for filing an Appeal Brief has previously been paid. The Commissioner is authorized to charge any additional filing fees or credit any overpayment to Deposit Account No. 50-2809.

REAL PARTY IN INTEREST

The real party in interest is Edwards Lifesciences Corporation, a California corporation having a place of business at One Edwards Way, Irvine, CA 92614-5686. Edwards Lifesciences Corporation is the Assignee of all rights in the application.

RELATED APPEALS AND INTERFERENCES

There are currently no appeals or interferences known to the appellant, the appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 36-44 are currently pending and of these claims, claims 36, 39 and 42 are independent. Claims 1-35 and 45 have been previously canceled. Claims 36-44 are rejected. Claims 36-44 are currently being appealed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. GROUND 1 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The first ground of rejection to be reviewed on appeal is the Examiner's rejection of claims 36-38 under 35 U.S.C. Section 112, first paragraph. The Examiner contends that the specification does not support "supportively engaging the medicament delivery catheter with the atrial septum" as claimed in claim 36" as recited in these claims.

II. GROUND 2 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The second ground of rejection to be reviewed on appeal is the Examiner's rejection of claims 36-38 under 35 U.S.C. Section 112, first paragraph. The Examiner contends that the specification does not support a "medicament delivery catheter".

III. GROUND 3 – REJECTION OF CLAIMS 42-44 UNDER SECTION 102

The third ground of rejection to be reviewed on appeal is the Examiner's rejection of Claims 42-44 under 35 U.S.C. Section 102(e) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*).

IV. GROUND 4 – REJECTION OF CLAIMS 36-38 UNDER SECTION 103

Claims 36-38 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 6,161,543 to Cox et al. (*The Cox et al. Patent*) and U.S. Patent Application No. 2001/0049497 to Kalloo et al. (*The Kalloo et al. Publication*).

V. GROUND 5 – REJECTION OF CLAIMS 39 AND 40 UNDER SECTION 103

Claims 39 and 40 are rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in

combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 5,725,523 to Mueller (*The Mueller Patent)*.

VI. GROUND 5 – REJECTION OF CLAIM 41 UNDER SECTION 103

Claim 41 is rejected under 35 U.S.C. Section 103(a) as being anticipated by U.S. Patent No. 6,283,951 to Flaherty et al. (*The Flaherty et al. Patent*) in combination with U.S. Patent No. 6,645,199 to Jenkins et al. (*The Jenkins et al. Patent*), U.S. Patent No. 5,725,523 to Mueller (*The Mueller Patent)* in further view of U.S. Patent No. 5,607,421 to Jeevanandam et al. (*The Jeevanandam et al. Patent*).

RESPONSE TO EXAMINER'S ARGUMENTS

I. GROUND 1 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The Examiner apparently acknowledges the specification supports "supportively engaging the medicament delivery catheter with the atrial septum" as recited in claims 36-38 but now argues that this device would "have a catastrophic effect on the health of the patient."

The rejection under Section 112 is strictly a legal question based on the language present in the claims. This rejection is not based on how effective or harmful the device of claims 36-38 is. Even if the Examiner's line of reasoning were relevant to the rejection at hand, the Examiner's interpretation of the claims does not accurately reflect claim interpretation as currently embodied in the law. For example, the Examiner's interpretation requires that "the medicament delivery catheter" can ONLY refer to the outer portion of the device. There is simply no basis for this interpretation. In fact, the Examiner specifically acknowledges that there is support in the specification for a device that can both engage and further advance as recited in claims 36-38.

Therefore, it is requested that the Section 112 rejection of these claims be withdrawn.

II. GROUND 2 – REJECTION OF CLAIMS 36-38 UNDER SECTION 112

The Examiner apparently concedes that "medicament delivery catheter" is supported by the specification. However, the Examiner now argues that, under a selective and very narrow interpretation, other aspects of the claims do not make sense. Specifically, the Examiner argues that the ablating member 310′ cannot be considered part of the medicament delivery catheter. Figures 42a-42c clearly shows an ablation member that is part of the device 300′. While the ablation member may not be immovably fixed to the outer layer of the device 300′, it is still part of the catheter. The claims simply recite a broader wording than the Examiner suggests. For example, a

dependent claim could be properly added to recite that the medicament delivery catheter further comprised an ablation member. In this respect, the Examiner's interpretation of the claim and specification fail.

Therefore, it is requested that this Section 112 rejection of these claims be withdrawn.

III. GROUND 3 – REJECTION OF CLAIMS 42-44 UNDER SECTION 102

First, the Examiner again argues that column 2, lines 11-14 of *The Flaherty et al. Patent* discloses preventing medicament from passing between the tissue engaging surface and the tissue surface to a location outside of the sealed opening. However, this quote refers to a different embodiment in which a drug is simply embedded in a catheter wall or non-porous balloon. This is not the same as "preventing medicament from passing..." as recited in the claims.

Next, the Examiner argues that "if the [*Flaherty*] balloon prevents washout, it can be considered 'sealing'". While the *Flaherty* balloon may reduce washout, especially relative to a direct application of drugs, it does not necessarily follow that the *Flaherty* balloon also seals. For example, sealing may involve creating a barrier that prevents passage of material while preventing wash-out not does not necessarily require this. It could be achieved by numerous other techniques. In other words, the sealing and wash-out are not the same.

Therefore, it is requested that this Section 102 rejection against the present claims be withdrawn.

IV. GROUND 4 – REJECTION OF CLAIMS 36-38 UNDER SECTION 103

The Examiner again argues that *The Kalloo et al. Publication* discloses balloons for "supportively engaging the atrial septum at the opening with the medicament delivery catheter."

While the device of *The Kalloo et al. Publication* may include balloons, these balloons are not appropriate for use with the present invention as claimed. For example, the *Kalloo* balloons are sized and configured for use on an endoscope during entry into a stomach and therefore include a relatively large diameter, large thickness and greater distance between both balloons.

Simply placing these *Kalloo* balloons on a device appropriately sized for a cardiac procedure as the Examiner suggests will not result in a device that can engage and seal an atrial septum as claimed in claim 36 without some additional teaching as to how such an adaptation may be performed. The atrial septum is small and relatively delicate, requiring different design considerations than the larger and more rugged entry into the stomach.

The Examiner further argues that adapting the *Kalloo* balloons is "well within the scope of one or ordinary skill in the art," yet provides no proof for this assertion. Section 2142 of the MPEP states:

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that "**rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.**" *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at ___ , 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval). [Emphasis added]

The Examiner has provided no such rational underpinning to support his bald assertion that adapting a large stomach balloon for use in the small, delicate heart would be obvious. Instead, only a conclusory statement of this assertion is provided.

Therefore, it is requested that the Section 103 rejections be withdrawn.

V. GROUND 5 – REJECTION OF CLAIMS 39 AND 40 UNDER SECTION 103

The Examiner argues that because the entire *Flaherty* balloon is not porous, a vacuum source would not suck out or wash-out the medicament. The Examiner has provided no reference or other factual theory to back up this assertion. It is generally known that a vacuum will pull or draw in liquid, particles or other material, barring a seal or barrier in between the two. It is unclear how drugs excreted from a porous balloon without such a seal would fail to be sucked up by a nearby vacuum source.

Therefore, it is requested that the Section 103 rejections be withdrawn.

VI. GROUND 5 – REJECTION OF CLAIM 41 UNDER SECTION 103

The Examiner again argues that a suction cup is somehow equivalent to a vacuum port. Simply, cups and ports are structurally different devices. A suction cup is a concave structure that adheres to a surface only when pressed against it. In contrast, a vacuum port is generally an opening of a passage connected to a vacuum source. In this respect, a vacuum port can be easily and selectively engaged and disengaged while a suction cup cannot. Hence, the Examiner's comparison fails.

Therefore, it is requested that the Section 103 rejection be withdrawn.

VII. CONCLUSION

For at least all the reasons stated herein, it is submitted that the Examiner's rejection is erroneous. As a result, the Applicant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

Respectfully submitted,

Dated: June 18, 2008

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